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Docket No. 4175

METHOD AND SYSTEM FOR MANAGING BLOOD PRODUCTS

Reference to Appended Items

Reference is made to the microfiche appendix attached hereto and incorporated herein as a part thereof.

Reference is also made to SafeTrace Tx Table Administration Manual, Release v1.2.0.0 published November, 1999, SafeTrace Tx User's Guide, published November, 1999, and SafeTrace Tx Reference Manual, also published November, 1999, all published by Wyndgate Technologies of El Dorado Hills, California, said publications incorporated by reference herein.

Background and Field of Invention

This invention relates to blood product management and more particularly relates to a novel and improved computer programmable method and system for blood product management including cross-matching and compatibility testing of blood products as well as the ability to display information about a patient during the preparation of blood components prior to transfusion and which is specifically adaptable for use in hospitals, clinics and the like.

There is a long-felt need for a blood product management system to help prevent the release of unsafe, unsuitable or ineffective blood products to patients. In a hospital, when an order comes down from a given floor or section of the hospital requesting blood, it is communicated to the blood bank which is typically located at the hospital. The blood bank will search for a suitable product for the patient, i.e. a suitable red blood cell, and in many situations must cross-match the blood product requested with the blood of the patient. Once successfully cross-matched, the blood product is then selected and made ready for issue. Another order or request will then be transmitted when the blood product is actually needed at which time the cross-matched product is delivered to the responsible personnel for providing a blood transfusion for the patient.

It is important to control the compatibility of a blood component and patient's blood to ensure safe transfusion of the component to the patient. This requires tracking of the patient blood attributes and blood component attributes by their respective antigens and antibodies. In addition, it is desirable to incorporate a patient information toolbar into the computer program for displaying and controlling critical patient information during the preparation of blood products

prior to transfusion. This information includes patient special needs, patient comments, patient transfusion reactions, availability of autologous blood components, availability of directed blood components, significant antibodies, patient blood type, expiration of the current patient specimen, and reserved blood components.

The following definitions are given to assist in better understanding the system and steps followed in carrying out the present invention:

"Antigen": A substance that induces the formation of antibodies and assists the body to distinguish between itself and a foreign substance.

"Antibody": A protein produced by the immune system in response to the presence of an antigen.

"Blood Type Definitions": A blood type is a way to classify blood into various groups. A blood type is determined by the presence or absence of antigens on the red blood cells, and the presence of antibodies in the serum. A blood type definition in the computer database is the combination of antibodies and antigens for each blood group (ABO/Rh).

"Blood Component": A blood component, also referred to as "blood product", is one of the portions of a unit of whole blood. Whole blood contains red blood cells, white blood cells and

platelets suspended in a watery fluid called plasma. Blood components include red blood cells, plasma, platelets and cryoprecipitated antihemophilic factor (AHF).

"Significant Antibodies": Any antibody, other than those for A and B (which are expected), that might cause a serious ("hemolytic") reaction after transfusion of blood containing the corresponding antigen.

"Segment": A portion of the blood component that can be detached and subsequently used for testing.

"Product ID Tag": The Product ID Tag is attached to the blood product being processed or issued to a patient. It contains information about the patient and the blood product to help in the identification and validation of the patient and product. The Product ID Tag is one of the mechanisms that transfusion services and hospitals use to verify that the patient and the product are correctly matched before transfusion. A typical Product ID Tag consists of three different sections:

1. Patient Information Section. This section contains critical patient information necessary to identify the patient. It is used to identify the patient in regard to the hospital, blood type and blood antibodies, as well as special needs associated with the patient.

2. Product Information Section. This section contains relevant product specific information regarding unit of blood to which this section is physically attached. This section is used to identify the unit of blood, blood type, and antigens. In addition to the product information, it contains information regarding cross-match testing, and lists any prohibiting factors and comments relevant to issuing of this product to the patient identified in the Patient Section of the report.

3. Transfusion Information Section. This section is created for recording handwritten information during transfusion. This section is a form that is filled out by the technician before, during and after transfusion of the product attached to the report. This section is used to record relevant information to the transfusion process, which can later be entered into the computer program database.

In accordance with the present invention, there are specific requisites to reliable, secure cross-matching of certain blood products, namely, receiving an order for the blood product, tracking segments of the blood components in inventory, locating a specimen of the patient's blood and transferring it to a given location, which typically would be a lab or blood bank at the hospital where

the inventoried blood segments are located.

It is therefore an object and feature of the present invention to control the remote testing of compatibility of a blood product and patient specimen to ensure the safety of the blood component transfusion into the human body by using a segment of the blood product assigned at the lab and mixing it with a portion of the patient specimen so as to achieve efficiency in the delivery of blood components both for emergency and non-emergency situations.

Another object of the present invention is to provide a computer programmable system that enables remote testing of patient blood and a segment of the blood component intended for transfusion remotely through the steps of (a) assigning a blood product, which is typically stored at a central facility, to a patient for testing at the central facility and preparing a segment of the blood component; (b) transferring to the facility a blood specimen drawn from the patient; (c) testing the segment of the blood component assigned with the blood specimen drawn from the patient to determine their compatibility; (d) whether or not compatible, printing a product ID tag at the facility where the blood component is located; and (e) continuously tracking movement of the blood product and specimen between the central facility and hospital on a

database.

Another object and feature of the present invention is to track patient blood attributes and blood component attributes in such a way as to ensure that the attributes are compatible with each other as well as to ensure that the transfused blood component is compatible with the patient who is receiving the transfusion.

A further object of the present invention is to provide for a novel and improved method and means for displaying critical patient information during the preparation of blood products prior to transfusion so as to make readily available to the medical technician important current and historical information about the patient.

In accordance with the present invention, a programmable method of managing and tracking blood products is provided for use between a plurality of remote patient facilities and a central blood testing facility including the steps of obtaining a blood specimen from each patient who requires a blood reserve, selecting a blood product for cross-matching with each said patient specimen, cross-matching each said patient specimen and said blood product to determine their compatibility with one another, and providing a database for the entry of information pertaining to each patient. Preferably, the step of storing information is further

characterized by information relating to a patient's special needs, prior transfusion history, autologous blood availability and its location, blood type and patient specimen expiration date. Still further, the method is characterized by being able to record information as to the location and patient blood attributes in the database.

A programmable system has been devised for managing and tracking blood products between a central blood test facility and a plurality of remote facilities which includes means for recording information on a database which identifies each patient requiring a blood reserve, means for obtaining a blood specimen from each said patient, means for assigning a segment of a blood product for cross-matching and for cross-matching each said segment and patient specimen to determine their compatibility with one another, and means for identifying each segment and patient specimen determined to be compatible as well as storing same in the computer.

The above and other objects, advantages and features of the present invention will become more readily appreciated and understood from a consideration of the following detailed description of preferred and modified forms of the present invention when taken together with the accompanying drawings in which:

Brief Description of the Drawings

Figure 1 is a flow diagram of a centralized transfusion model with multiple hospitals;

Figure 2 is a flow diagram of a central facility and one of the hospitals illustrated in Figure 1 which illustrates the location of inventory, segments, patient specimens and patients;

Figure 3 is a flow diagram illustrating completion of remote cross-match testing;

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Figure 4 is a flow chart illustrating the logic used in a standard compatibility test;

Figure 5 is a flow chart illustrating the logic used in a patient auto-compatibility test;

Figure 6 is a flow chart illustrating the logic used in a product auto-compatibility test;

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Figure 7 is a flow chart illustrating the logic used in an emergency patient product compatibility test;

Figure 8 is a screen display of a patient bar in accordance with the present invention;

Figure 9 is a flow chart illustrating the logic used in button s of the patient bar;

Figure 10 is a flow chart illustrating the logic used in button c of the patient bar;

Figure 11 is a flow chart of the logic used in connection with the button x of the patient bar;

Figure 12 is a flow chart of the logic used in button a of the patient bar;

Figure 13 is a flow chart of the logic used in button d of the patient bar;

Figure 14 is a flow chart of the logic used in button aby of the patient bar;

Figure 15 is a flow chart of the logic used in conjunction with blood-type button "o-pos" of the patient bar;

Figure 16 is a flow chart of the logic used in conjunction with the specimen expiration date button of the patient bar;

Figure 17 is a flow chart of the logic used in conjunction with button r of the patient bar;

Figure 18 is a flow chart showing product selection steps followed in remote cross-match testing;

Figure 19 is a flow chart illustrating test result entry steps related to remote cross-match functionality;

Figure 20 is a screen display of patient information;

Figure 21 is a screen display of component blood attribute information; and

Figure 22 is a screen display of information stored in tracking the location of blood components.

Detailed Description of Preferred Embodiment

The preferred form of invention allows a blood bank to maximize its efficiency in cross-matching a blood component to a patient for transfusion. This efficiency will result in improved patient care by the blood bank and the hospital. This process allows timesaving during the testing and the time needed to transfer the blood product to the patient site. The requirements for this process are to have complete tracking of the blood component, the blood component segment, the patient, and the patient specimen. Any one of these requirements not met could result in a mismatch of the component and the patient which can result in serious health problems to the recipient of the blood.

The remote cross-match capability allows a group of hospitals to be organized to include a common or centralized facility or transfusion service to share a common laboratory to perform blood testing as well as cross-match work for all hospitals in the group. This reduces the amount of staff required at the hospitals. Typically, each hospital will have only a stat laboratory to handle its emergency patient/product cross-match needs. Figure 1 depicts a typical centralized or common transfusion model L having a "centralized processing laboratory 1" with multiple hospitals H.

In accordance with the present invention, the hospital is able to track the location of the patient specimen, segment of the blood component and the blood component itself. The cross-match compatibility testing is completed using the segment of the blood component and the patient specimen while the blood component resides at a different location. This process will allow efficient and timely delivery of blood components in both emergency and non-emergency situations.

Before a remote cross-match can be performed, the following conditions must exist: (a) the patient exists in the system with current visit information, (b) the patient has a current blood specimen and the specimen has been transferred to the central facility, (c) the patient has an order for a blood component and a cross-match test, (d) the blood component has an available segment, and (e) the blood component that will fill the order resides at the hospital where the patient is located and a segment of that blood component is at the central facility with laboratory L. Figure 2 depicts a central facility including the laboratory L and one of the hospitals H and where the inventory, segments, patient specimens and patients are located.

Completing the remote cross-match is the process wherein a lab technician at the central

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laboratory L assigns a blood component identified by a segment to a patient specimen. Once the assignment is made, the lab technician proceeds to test the segment with the patient specimen to determine compatibility. Upon completing the cross-match test, the lab technician enters the results into the computer program database. Once the results are saved, the product ID tag will be printed at the location of the blood component L and the blood component will be ready to issue to the patient if the patient and product are compatible.

As shown in Figure 3, the laboratory technician at the central facility assigns a blood component identified by the segment to the patient. During this product selection process, as shown in Figure 18, the computer program runs the following checks: (a) verifies that the product ID of the entered component matches the selected order item; (b) if the entered component has an active segment, then the segment must be entered by clicking the segment command button; (c) verifies the location and status of the segment (the segment must be available and located at the facility making the selection); (d) verifies the state of the component; and (e) if the entered component is reserved, make sure that the component is reserved for the designated patient. In testing, the laboratory technician performs the cross-match test at the work

bench. Upon completion of the serological testing, the technician enters the results into the computer program database. The computer program database forces the technician to verify the patient specimen identifier and the blood component segment identifier before allowing them to record the results of the test. During the result entry process, as shown in Figure 19, the computer program runs the following checks: (a) verifies that the specimen is at the user's location for abbreviated or unabbreviated cross-match test and (b) verifies that the segments are at the user's location for abbreviated or unabbreviated cross-match test.

When the technician has completed the data entry of the test results, the results are written to the database. For each completed cross-match test, a product ID tag is printed at the facility where the blood component is located. Any blood components associated with cross-match tests that were compatible will be available for issue at the location of the patient and blood component.

Patient/product compatibility is carried out by determining the patient blood attributes and the blood component attributes by their respective antigens and antibodies. As shown in Figure 4, standard compatibility compares the patient's antigens with the blood component's corresponding antibodies and blood component's antigens with the

patient's corresponding antibodies. When comparing the corresponding antigen and antibody pairs, the incompatibility is determined by a positive presence in both the antigen and antibody. Further, the blood component antigen or antibody may require confirmation by the blood bank for the compatibility comparison to be successful. As illustrated in Figure 4, when this situation occurs, the user is alerted that a blood component's blood attribute has not been confirmed by the blood bank. If one-half of the pair is missing either from the patient or the blood component, the user is alerted that a blood attribute is missing; further testing on the patient's blood or the blood component is required to determine compatibility.

The following Table illustrates a sample compatibility test between the patient and the blood component:

Table I

Patient Antibody	Component Antigen	Component Attribute Confirmed	Compatible
K Positive	K Positive	N/A	No
K Positive	K Negative	Yes	Yes
K Positive	K Negative	No	Unknown
K Positive	K Unknown	N/A	Unknown

Figure 4 illustrates the logic employed in carrying out standard compatibility tests.

Auto-compatibility compares the antigens

and antibodies within either the patient or within the blood component. The new or updated antigen is compared with the corresponding antibody or the new or updated antibody is compared with the corresponding antigen. If both the antigen and antibody have a positive presence, then the patient or blood component is incompatible with itself. When this situation occurs, the computer program database alerts the user that the new or updated blood attribute is not compatible with the existing blood attribute information. These checks help reduce data entry errors.

Figure 5 illustrates the logic used in testing patient auto-compatibility, and Figure 6 illustrates the logic used in testing blood component auto-compatibility.

When the patient is unknown to the computer system or the patient is known but there is no current specimen and/or no blood type test on the current specimen, as illustrated in Figure 7, an emergency compatibility check is run to determine if

the blood component selected can be issued to the patient. The emergency issue results are controlled by the users to fit the industry defined standards for a given product ID. The following Table illustrates a sample of the rules that may be used by a blood bank:

Table II

Product ID	Age Operator	Age	Gender	ABO	RH
RBC	Greater than	50	Female	0	
RBC	Less Than	50	Female	0	Neg
RBC			Male	0	
FFP				AB	
Gran	Greater than	50	Female	0	
Gran	Less Than	50	Female	0	Neg
Gran			Male	0	

There is illustrated in Figure 8 a patient bar P which affords access to information stored in the computer pertaining to each patient and blood products for that patient in response to passing in a patient identification number used to uniquely identify a patient in the database. Figure 20 illustrates a typical patient profile screen which displays the patient bar P in conjunction with a particular patient having a patient identification

number as displayed at "Patient ID".

Button captions are driven by the current state of patient information which is drawn from the database.

Specifically, the button s provides a visual indication that the patient has special needs. If the button displays as a capital "S", then there are active special needs for the patient; otherwise, a lower case "s" means no current special needs exist, as illustrated in Figure 8. Clicking the button s accesses the patient's special needs information stored in the computer on a patient profile form. Patient special needs information is defined by the client and normally includes clinical information about the patient that constrains the scope of blood products which are appropriate for use by a particular patient. These needs are most often critical safety indicators which must be considered when selecting blood products for patient transfusion. Failure to consider patient special needs when selecting and testing blood products can

be considered as a serious safety issue.

A patient "comments" button c provides a visual indication of patient comments. Again, if the button c displays as a capital "C", then there are active comments; otherwise, a lower case "c" means no current comments exist, as illustrated in Figure 9. Clicking the button C accesses any patient comments as stored in the computer.

Patient transfusion reaction information is used to document clinical information about the patient when the patient has had a reaction to a prior transfusion. This type of reaction is often followed up by subsequent post-transfusion testing to help determine the possible causes of the reactions. A reaction history may constrain the scope of blood products which are appropriate for use by a particular patient. Failure to consider prior transfusion reaction information when selecting and testing blood products may be considered a serious issue.

The button x provides a visual indication

of transfusion reaction information of a patient. Thus, an upper case "X" indicates that the patient has had a transfusion reaction; otherwise, a lower case "x" means no transfusion reaction has been recorded in the system as illustrated in Figure 10. Clicking the button X accesses any transfusion reaction information stored in the computer.

The button a provides a visual indication of the availability of at least one unit that is identified as an autologous donation for the patient which has not expired, not transfused, not shipped, not discarded, not consumed or crossed-over. If the button displays a capital or uppercase "A", there is at least one such donation in inventory; otherwise, a lower case "a" means "none", as illustrated in Figure 11.

Autologous components are blood products (i.e. whole blood) which the patient has donated specifically for his or her personal use. A patient who is scheduled for surgery where a transfusion may be required will often donate blood prior to

surgery. This blood is categorized as autologous and is the preferred choice for transfusion.

The button d is a visual indication of a directed donation for the patient, not expired, not transfused, not shipped, not discarded, not consumed or crossed-over. If the button displays an uppercase "D", there is at least one such donation in inventory; otherwise, a lower case "d" means "none", as illustrated in Figure 12.

Directed components are blood products (i.e. whole blood) which a donor has specifically designated for a particular patient's use. A patient who is scheduled for surgery where a transfusion may be required may have relatives or friends donate compatible blood specifically for use by a patient. This blood is categorized as directed and if deemed compatible is often preferred over other blood products available in the general inventory.

Significant antibodies indicate that the patient has had prior blood testing which has

indicated the presence of unexpected or clinically significant antibodies, clinically significant antibodies being user-defined. The presence of these antibodies should be considered prior to issuing blood products for patient transfusion. The patient's blood attributes may constrain the blood products which are appropriate for use by the patient and/or require additional testing or modifications of blood products prior to transfusion.

The button aby is an indication of whether the patient has unexpected antibody information. Referring to Figure 14, if the button displays as upper case "ABY", there is information regarding unexpected antibodies; otherwise, lower case "aby" means "none" as illustrated in Figure 14.

The next button presents the blood type of the patient, such as, "O Pos". This requires that the patient's blood type has been previously tested or was entered into the patient record. The blood type text contains the ABO and Rh components. The

text for this is user modifiable but is generally standardized for ABO values, of "A,B,AB,O" and Rh values "POS" and "NEG". Therefore an example of a blood type caption presented might be "A POS". If the patient's blood type is unknown, the caption is left blank. Clicking on the blood type button accesses that information stored in the computer.

The next button displays a patient's specimen expiration date. If there is a specimen that is current, active and available, then its expiration date displays as illustrated in Figure 15. If no current active specimen is recorded for the patient or the specimen does not have an available status, no data is displayed on this button. Clicking on the button accesses the patient's specimen information stored in the computer.

Reserved components are blood products which have been specifically linked for a particular patient's use. The last button "r" indicates whether reserved components are available for the

patient. If the button displays as uppercase "R", then there is at least one such component in inventory; otherwise, "r" means none, as illustrated in Figure 17.

In practice, information relating to patient, blood products, component attributes may be recorded or stored in the database in the manner illustrated in Figures 20 to 22. As previously noted, Figure 20 is a screen display of patient information including the patient bar P, Figure 21 is a screen display of component blood attributes, and Figure 22 illustrates information stored in tracking the location of blood components.

As soon as a blood component is received, it is assigned to a location within the central test facility. Throughout the life span of the blood component, the location of the component must be recorded, as illustrated in Figure 22, before it can be transferred to another part of the facility or shipped outside the facility. If it is necessary to process the blood component, the computer verifies

that the blood component is at the correct location for the work to be performed. Patient specimens and blood component segments are managed in a similar manner. Whenever a patient specimen or component segment is entered in the computer, it must be assigned to a location within the facility. The specimen or segment can only be used in processing if it resides at that location. If the specimen is needed by another facility, the transfer must be recorded in the computer system before it can be used by the receiving facility.

From the foregoing, Figures 1, 2 and 3 are intended to illustrate what is meant by "remote cross-matching" in which the cross-matching of each blood product and patient specimen is done at a facility remote from the patient. This avoids the necessity of maintaining a staff at each hospital but can only be done by maintaining records in the computer of the identity and location of the blood products and specimens.

Figure 4 is intended more to show the

logic for determining compatibility of a given blood product and specimen based on blood attributes as illustrated in Figures 5 and 6. Strictly speaking, this is not cross-matching but can be used as a preliminary step for cross-matching. Thus, the system is capable of verifying the updates of blood attributes of the patient as well as blood products to assure that they are compatible as more information becomes available. In conjunction with physical cross-matching, blood attribute determination is helpful in ascertaining the compatability of a given blood product and specimen.

Figure 7 is intended more to show the alternative of emergency supply of blood where there is no time to cross-match or identify the patient and is intended more as a means of assuring that the blood made available can be used with virtually any patient.

It is therefore to be understood that while preferred and modified forms of the present invention are herein set forth and disclosed, other

modifications and changes may be made therein without departing from the spirit and scope of the present invention as defined by the appended claims and reasonable equivalents thereof.